Attorney's Docket No. P[redacted]16156.002 (35784/239423)

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Frey II
Appl No.: 09/976,620
Filed: October 12, 2001
For: METHOD FOR TREATING ISCHEMIC EVENTS AFFECTING THE CENTRAL NERVOUS SYSTEM

Confirmation No.: 1674
Group Art Unit: 1647
Examiner: Christopher J. Nichols

April 25, 2003

Commissioner for Patents
Washington, DC 20231

RESPONSE TO RESTRICTION REQUIREMENT

This is in response to the Office Action dated March 13, 2003, in which the Examiner has required restriction between Group I, namely claims 1-12, and Group II, namely claims 13-26. Applicant hereby provisionally elects with traverse to prosecute the claims of Group 1 (claims 1-12) and expressly reserves the right to file divisional applications or take such other appropriate measures deemed necessary to protect the inventions in the remaining claims.

The Examiner has reasoned that the inventions of Group I and Group II are directed to methods that are "distinct both physically and functionally, and are not required one for the other" (Office Action mailed March 13, 2003, at page 2, item 3). However, Applicant respectfully notes that while the preamble for claims 1-12 encompasses a broader scope of clinical objectives than does the preamble for claims 13-26, the method that is used to accomplish the clinical objectives recited in both of these preambles is the same.

The Group I claims recite a method for preventing or reducing ischemic damage in the central nervous system of a mammal. The method comprises administering a therapeutically effective amount of insulin-like growth factor I (IGF-I) intranasally to the mammal, where the therapeutically effective amount of IGF-I comprises about 0.1 mg to about 3.0 mg IGF-I per kg body weight of the mammal. This IGF-I administration protocol has utility in treating a mammal that has experienced an ischemic event that results in ischemic damage in the central nervous system. This utility is the basis for the Group II claims.

Applicant respectfully submits that the Group I and Group II inventions are in fact related by virtue of their requirement for the use of the same IGF-I administration protocol, i.e., intranasal administration of a therapeutically effective amount of IGF-I that comprises about 0.1 mg to about 3.0 mg IGF-I per kg body weight of the mammal. Contrary to the statement in the

Office Action that the Group I and Group II inventions have acquired a separate status in the art (Office Action, page 3, item 5), the integral relationship between these two groups of claims has resulted in their identical classification in class 514, subclass 2. Furthermore, Applicant submits that a search for the method of intranasally administering an amount of IGF-I in the range of about 0.1 mg to about 3.0 mg per kg body weight of a mammal would uncover prior art directed to the clinical objectives recited in both groups of claims. Therefore, consideration of these claims at the same time would not result in a search that was unduly burdensome for the Examiner.

In view of these remarks, Applicant respectfully submits that this restriction is improper, and respectfully requests the Examiner to withdraw the restriction requirement. Should the Examiner have further questions or comments with respect to examination of this case, it is respectfully requested that the Examiner telephone the undersigned so that further examination of this application can be expedited.

It is not believed that extensions of time or fees for net addition of claims are required beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

Leslie T. Henry

Leslie T. Henry
Registration No. 45,714

CUSTOMER NO. 00826
ALSTON & BIRD LLP
Bank of America Plaza
101 South Tryon Street, Suite 4000
Charlotte, NC 28280-4000
Tel Raleigh Office (919) 862-2200
Fax Raleigh Office (919) 862-2260

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Washington, DC 20231 on April 25, 2003.

Lynda-Jo Pixley

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